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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,413	04/19/2001	Marco Falciani	203970US6PCT	5932

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EXAMINER

BASICHAS, ALFRED

ART UNIT PAPER NUMBER

3749

DATE MAILED: 11/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/807,413	Applicant(s) FALCIANI ET AL.	
	Examiner Alfred Basichas	Art Unit 3749	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6, 7, 9, 10, 12, 14, 16, 18-20, 22, 23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 7, 9, 10, 12, 14, 16, 18-20, 22, 23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 6, 7, 9, 10, 12, 14, 16, 18-20, 22, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scharf (5,484,431) in view of Kopfer (5,088,996) and Gilford (3,647,386).

a. Scharf discloses substantially all of the claimed limitations, among other things, a method and apparatus for a bag 10 for preserving and transporting a soluble sterile (see at least col. 3, lines 50-51) product in powder form (see at least col. 3, lines 51-52) and for reconstituting in the bag a ready to use solution with a predetermined concentration of the sterile product (see at least col. 3, lines 52,53), the bag being of polyolefin construction (see at least col. 4, lines 4-8), sealed at its periphery (see at least fig. 1) to define a sterile closed space and having at least one port 24,26,28,34 also of polyolefin construction defining a passageway having two ends that open inside and respectively outside the bag, the passageway being closed by a syringe pierceable membrane for introduction of a solvent into the bag (see at least col. 5, lines 7-13), wherein the bag contains an amount of the sterile product in powder form (see at least col. 3, lines 50-51), and wherein the at least one port of the bag is plugged by a plug 25,27,29.

b. While Scharf does not specifically recite that the bag is hermetically sealed, it is inherent as such a condition would be necessary for at least two reasons. First, for the contents to remain sterile it would be necessary for the container to be hermetically sealed, so as to keep contaminants out. Second,

once the solution is reconstituted with sterile water, the container would have to be able to contain the liquid without leaking, thus requiring that the container be hermetically sealable.

c. Furthermore, Scharf does not specifically recite that the same port may be used for withdrawal of the ready to use solution from the bag, that the bag is “adapted” to give with the solvent and within the bag the reconstituted ready to use solution only partially filling a capacity of the bag, the specific capacity to which the bag is filled, the bag containing multiple of single doses.

i. As regards the same port being used to both inlet and outlet, Kopfer teaches a sterile container 26 (glass vile) including a syringe 20 and a pierceable cap 54. Kopfer specifically recites that the powder in the container may be reconstituted by introducing a liquid into the container using the syringe, shaking the contents and extracting the solution using the same syringe. Kopfer clearly teaches a prior art method and apparatus for reconstituting a sterile powder in a sterile environment. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the utilization of the same port for both inlet and outlet as taught by Kopfer into the invention disclosed by Scharf, so as to provide for a sterile environment in which to combine sterile components.

ii. As regards partially filling the bag and the claimed range, adding less than the full capacity of the bag in order to allow for room to shake is

well within the knowledge and ability of one of ordinary skill in the art. It is notoriously well known that providing room in a container for greater turbulence and therefore the "sloshing" of the liquid provides for more effective dissolving of the powder in the liquid. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided for only filling the bag with less than the capacity of the bag of the ready to use solution into the inventions of Scharf in order to provide room to shake the contents of the bag. Further as regards the claimed range, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have incorporated the claimed range into the invention disclosed by the above mentioned combination, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

iii. As regards the bag containing multiple doses, Gilford discloses a hermetically sealed polyolefin bag for preserving and transporting sterile medication specifically for removal in plural doses. This type of arrangement and method is well known in the art for the purpose of sampling the contents by removing separate doses. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated removal in plural doses, as taught by

Gilford, into the inventions disclosed by Scharf, for the purpose of sampling the contents of the bag.

Response to Arguments

5. Applicants' arguments with regard to the rejected claims, filed September 13, 2005, have been considered, but are not deemed fully persuasive.
6. In response to applicant's argument that Scharf and Gilford is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both references involve sterile containment and containers.
7. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).
8. In response to applicant's argument regarding the term "dose." It should be noted that the examiner gives each term the broadest reasonable definition. As such, since applicants have provided a dictionary definition, applicants' attention is directed to "Merriam-Webster Online" where the term "dose" is also defined as "a portion of a

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substance added during a process.” Thus, removing samples, as prescribed by Gilford satisfies this definition.

9. Contrary to applicants' arguments the term “common sense” does not appear anywhere in the office action. In response to applicant's challenge to the examiner's assertion that leaving room at the top is well known and request that the examiner provided references to support the contention several references have been cited. Of particular interest and relevance Fuller (5,000,314) recites a “unit dose package” for reconstituting a powder solution and providing space in the container to aid in the mixing (see at least col. 3, lines 52-65). Two additional patents issued to Diesso also discuss the importance of leaving additional room to aid in the mixing of two components (6,695,901 – see at least col. 9, lines 1-11, and 6,352,585 – see at least col. 7, lines 49-59). Applicant is reminded that Diesso is relevant and reasonably pertinent to the particular problem with which the applicant was concerned; specifically, mixing of the two components.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alfred Basichas whose telephone number is 571 272 4871. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ira Lazarus can be reached on 571 272 4877. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872 9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center telephone number is 571 272 3700.

November 2, 2005


Alfred Basichas
Primary Examiner